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Original Research

Comprehensive Shielding System Enhances Radiation Protection for Structural Heart Procedures

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ABSTRACT

Background: This study of radiation exposure (RE) to physicians performing structural heart procedures evaluated the efficacy of a novel comprehensive radiation shield compared to those of traditional shielding methods. A novel comprehensive shielding system (Protego, Image Diagnostics Inc) has been documented to provide superior RE protection during coronary procedures compared to that provided by a standard "drop down" shield. The purpose of this study was to assess the efficacy of this shield in transcatheter aortic valve replacement (TAVR) procedures, which are associated with disproportionate RE to operators.

Methods: This single-center, 2-group cohort, observational analysis compared RE to the primary physician operator performing TAVR using the Protego shield (n = 25) with that using a standard drop-down shield with personal leaded apparel (n = 25). RE was measured at both thyroid and waist levels with a real-time dosimetry system (RaySafe i3, RaySafe) and was calculated on a mean per case basis. Data were collected on additional procedural parameters, including access site(s) for device implantation, per case fluoroscopy time, air kerma, and patient factors, including body mass index. Between-group comparisons were conducted to evaluate RE by group and measurement sites.

Results: The Protego system reduced operator RE by 99% compared to that using standard protection. RE was significantly lower at both the thyroid level (0.08 ± 0.27 vs 79.2 ± 62.4 μSv; $P < .001$) and the waist level (0.70 ± 1.50 vs 162.0 ± 91.0 μSv, $P < .001$). "Zero" total RE was documented by RaySafe in 60% (n = 15) of TAVR cases using Protego. In contrast, standard protection did not achieve zero exposure in a single case.

Conclusions: The Protego shield system provides superior operator RE protection during TAVR procedures. This shield allows operators to work without the need for personal lead aprons and has potential to reduce catheterization laboratory occupational health hazards.

Introduction

Catheterization laboratory radiation exposure (RE) poses occupational health hazards to physicians and staff owing to risks of direct radiation–induced injuries, including cataracts and cancers.[1-11] A further concern is the high rate of orthopedic maladies related to the cumulative burden of bearing the weight of heavy lead aprons necessary to mitigate RE.[1-3,12,13] The need to enhance safety in the fluoroscopy laboratory has been highlighted in position papers published by societies representing interventional physicians,[1-3] and experts have emphasized the need for protective strategies to achieve "as close to a zero radiation exposure work environment as possible and ultimately eliminate the need for personal protective apparel and prevent its orthopedic and ergonomic consequences."[1,2]

A novel comprehensive shielding system (Protego, Image Diagnostics Inc), has been demonstrated to provide excellent radiation protection,[14-16] a magnitude of protection sufficient for the State of Michigan to certify it for use without operators needing to wear personal lead aprons.[17] Clinical studies during coronary angiography and percutaneous coronary interventions (PCI) have shown that it provides superior protection from RE, reducing primary physician operator RE by >99% compared to traditional methods employing "drop down" shields, thereby facilitating procedural performance without the operator wearing lead aprons.[18] Percutaneous structural heart procedures have been associated with disproportionately high operator RE, attributable to prolonged fluoroscopy times associated with procedural complexity.[19-27] The purpose of this study was to assess the efficacy of the Protego shield in structural heart procedures.

Abbreviations: PCI, percutaneous coronary interventions; RE, radiation exposure; TAVR, transcatheter aortic valve replacement.

Keywords: occupational hazard; occupational health; radiation safety.

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Methods

Study design

This single-center, observational analysis of a 2-group cohort of consecutively enrolled patients comparing RE to the primary physician operator performing transcatheter aortic valve replacement (TAVR) using the Protego shield (n = 25) with that using a standard drop-down shield with personal leaded apparel (n = 25) was performed in a catheterization laboratory equipped with a floor-based single plane C-arm (Axiom Artis, Siemens). All patients, in both arms of the study, had femoral artery access for the purposes of transcatheter heart valve delivery and a single radial artery access site as well. RE was measured at both the thyroid and waist levels with a real-time dosimetry system (RaySafe i3, RaySafe) and was calculated on a mean per case basis. Data were collected on additional procedural parameters, including access site(s) for device implantation, per case fluoroscopy time, air kerma, and patient factors, including body mass index. Between-group comparisons were conducted to evaluate RE by group and measurement sites.

Protego radiation protection system

The Protego radiation shielding system has been previously described[14-16] and consists of a combination of rigid shields above and below the table, integrated with interconnecting flexible radiation-resistant drapes (Figure 1). The key elements include the following: (1) upper shield located above the table with an angulated design to passively accommodate unimpeded C-arm motion; this component is connected to an articulated support arm that can be suspended from a mobile pedestal platform or the ceiling; (2) lower shield located below the table; (3) accessory side shield that affixes to the operator's side of the system and extends the umbrella of protection; (4) flexible radiation-resistant drapes that interconnect to the fixed shields and overlap with similar drapes with portals for vascular access; (5) specially designed arm board with in-built radiation drapes for radial access; and (6) disposable sterile drapes that cover the fixed and flexible components. Recent refinements include enhanced protective layers on the radial arm board and modified patient radiation drapes to eliminate RE leaks.

Statistical analysis

T tests were conducted to evaluate differences in RE by group (control vs Protego) and access site (waist and thyroid). Data were entered and analyzed using IBM SPSS version 25 (IBM Corp, Released 2017; IBM SPSS Statistics for Macintosh, version 25.0, IBM Corp). The alpha level was set at 0.05. The Bonferroni correction (α/k) was applied to adjust for experimenter-wise error, with multiple comparison tests on the same participants resulting in an adjusted alpha of 0.025 (0.05/2).

Results

Data were compared between cases employing the Protego shield (n = 25) and those with traditional shielding (n = 25). There were no differences between the groups with respect to procedural

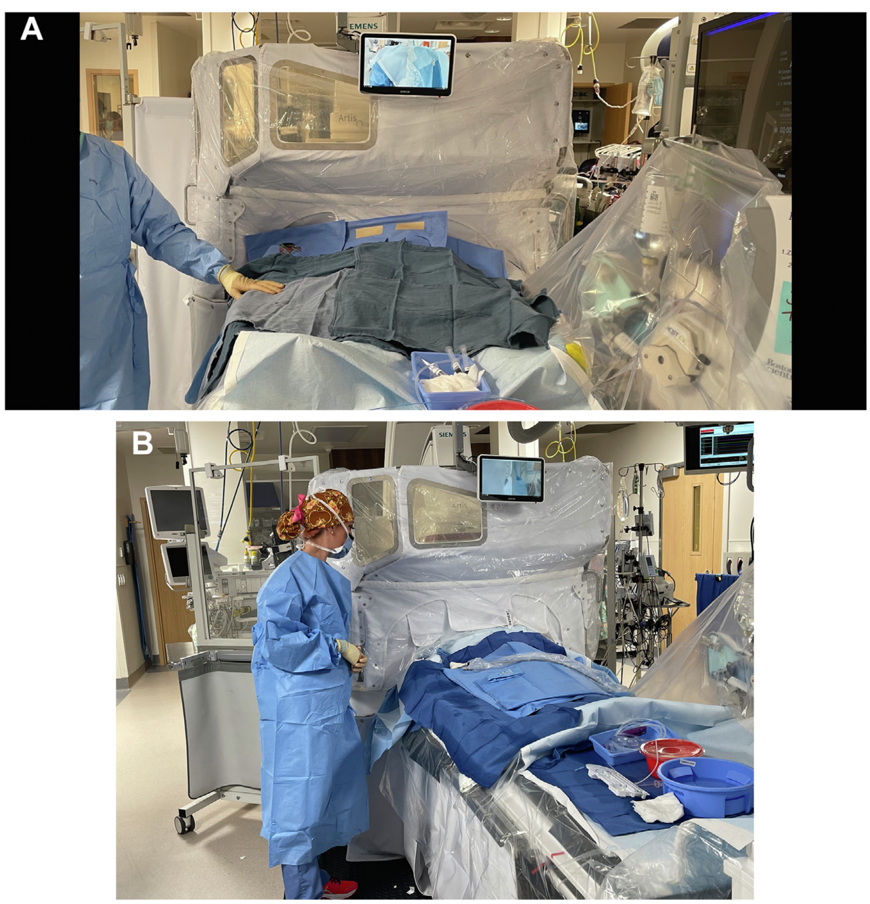


Figure 1.
The radiation shielding system. (**A**) The Protego radiation shielding system consists of a combination of rigid shields above and below the table as well as interconnecting flexible radiation-resistant drapes. (**B**) Shield in clinical use.

Table 1. Patient and TAVR procedural characteristics.

	Control group, n = 25	Protego group, n = 25
Patient characteristics		
Age, y	79.2	80.1
Female	12 (48)	6 (24)
Male	13 (52)	19 (76)
Body mass index, kg/m^2	29.3 ± 4.55	27.6 ± 5.05
Procedural characteristics		
Access site—radial	25 (100%)	25 (100)
Access site—femoral	25 (100%)	25 (100)
Fluoroscopy time, min	13.9 ± 5.8	14.0 ± 11.3
Air kerma, mGy	598.7 ± 337.2	768.7 ± 650.4
DAP, Gy·cm^2	86.8 ± 71.1	93.9 ± 42.5
Dose/DAP, 1/cm^2	0.0068	0.0082
RaySafe badge dose		
Waist badge, mrem	16.2 ± 9.10	0.07 ± 0.150
Thyroid, mrem	7.92 ± 6.24	0.008 ± 0.027
Waist badge, μSv	162.0 ± 91.0	0.70 ± 1.50
Thyroid, μSv	79.2 ± 62.4	0.08 ± 0.27

Values are expressed as n (%) or mean ± SD.
DAP, dose area product; TAVR, transcatheter aortic valve replacement.

and demographic parameters (Table 1). In both cohorts, identical number of procedures were performed using both femoral and radial access. The full range of C-arm angulations was easily accommodated, and in no case did the shield system impair procedural performance with respect to vascular access, utilization and manipulation of catheter equipment, or observation of and communication with the patient.

Overall, the Protego shield reduced operator RE by 99% compared to cases with traditional shielding alone (Central Illustration). RE was strikingly low in absolute terms and Protego protection was superior at both the thyroid (0.08 ± 0.27 vs 79.2 ± 62.4 μSv; $P < .001$) and waist levels (0.70 ± 1.50 vs 162.0 ± 91.0 μSv; $P < .001$) (Table 2). Remarkably, "zero" total RE was documented by RaySafe in 60% (n = 15) of TAVR cases using Protego. In contrast, standard protection did not achieve "zero" exposure in a single case.

Discussion

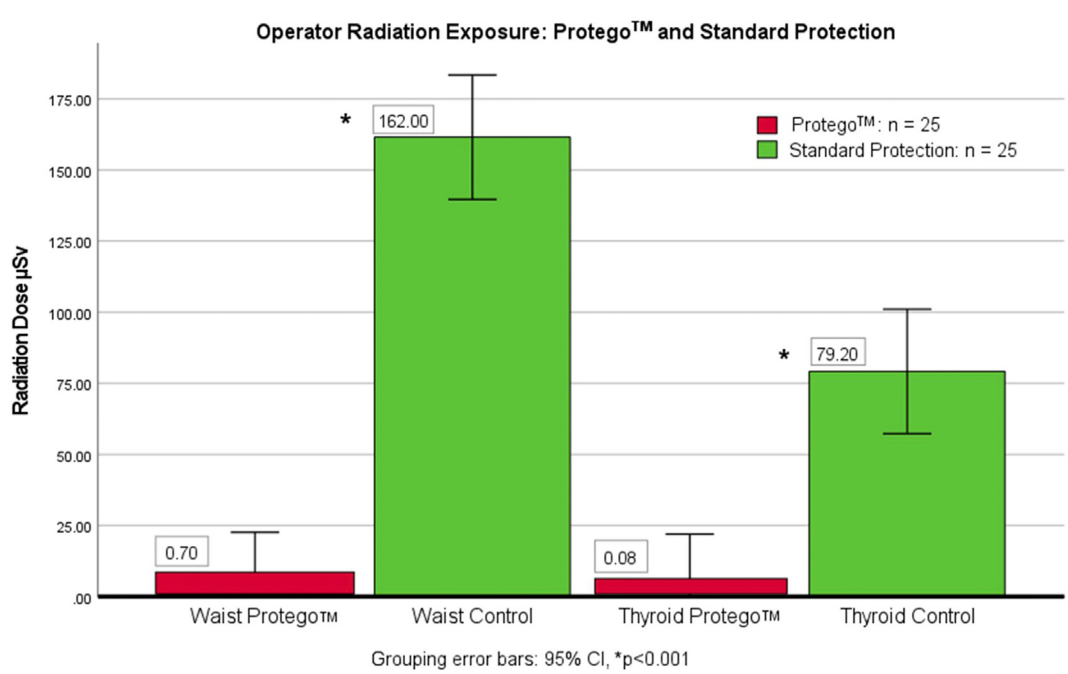
Observations from the present study demonstrate that the Protego radiation shielding system provides superior physician RE protection for structural heart cases. This shield allows the operator full procedural performance, including radial and femoral vascular access, and accommodates the full range of C-arm angulations. Given its capabilities and validation to allow operators to perform procedures without the need for orthopedically burdensome lead aprons, this protective approach has potential to reduce catheterization laboratory occupational health hazards

The present findings in structural heart cases are consistent with and extend those of recent reports in coronary angiography and PCI procedures,[14-16] documenting that the Protego shield provides exceptional protection with a strikingly low RE that is vastly superior to traditional shielding despite comparable fluoroscopy times.

RE in structural heart procedures

In general, increased volume and complexity of procedures intensify the magnitude of RE and its associated health risks. Structural heart cases may entail substantial complexity and have been shown to be associated with increased procedural and fluoroscopy times and, therefore, excess RE compared to routine coronary procedures. Therefore, previous coronary data[14-16] examining the potential benefit of this advanced radiation shielding system should not necessarily serve as a surrogate for TAVR and complex structural interventions. The current study addresses any potential differences in the radiation reduction efficacy of the Protego shielding system.

A large multicenter study observed that interventional radiologists received the highest RE; however, on a procedural basis, structural or valvular cardiac interventions were associated with the greatest RE.[19] Increased procedural complexity and duration as well as radiation attenuation and scatter predict increased patient RE during TAVR.[20]



Central Illustration.
Radiation exposure with Protego vs standard protection. Real-time RaySafe dosimetry comparison between transcatheter aortic valve replacement cases performed with Protego and standard protection. Operator mean radiation exposure per case is described in microsieverts measured at the waist and thyroid for both groups.

Table 2. Mean, median, SD, and interquartile ranges for microsieverts (μSv) of radiation exposure by group and access site.

	Waist		Thyroid	
	Protego	Standard protection	Protego	Standard protection
N				
Valid	25	25	25	25
Missing	0	0	0	0
Mean	0.70	162.0	0.08	79.2
Median	0.00	144	0.00	73
SD	1.50	91.0	0.27	62.4
Percentiles				
25	0.000	106.50	0.000	37.00
50	0.000	144.00	0.000	73.00
75	1.000	170.00	0.000	105.00

Operators performing TAVR were exposed to very high RE compared to that during routine diagnostic angiography (~42 fold), PCI (~14-fold), and peripheral interventions (~7 fold).[21] TAVR via "alternative access" has been associated with higher operator RE compared to that with the transfemoral approach, which may be in part related to suboptimal shielding equipment in hybrid operating rooms.[22] Although recent innovations in catheter technology and imaging have reduced fluoroscopy times for TAVR cases, percutaneous mitral procedures continue to require greater time and engender greater RE.[23] Recent attention has also been paid to RE among interventional echocardiographers and anesthesiologists, crucial team members who work in an exposed and relatively unprotected position at the head of the table nearest the x-ray source.[24-28]

Comprehensive radiation protection to mitigate occupational health risks

The occupational health hazards associated with working in the fluoroscopic laboratory are well documented and are the subject of increasing concern and attention.[4-12] Chronic occupational exposure to ionizing radiation may directly induce disease, including cataracts, cancer induction, and vascular injury predisposing to atherosclerosis. RE imposes "indirect" induced injury owing to the necessity of wearing orthopedically burdensome protective lead aprons.[1-4]

The fundamental axiom of radiation safety is based on the principle of "ALARA": as low as reasonably achievable.[29] The advent of novel shielding as described herein appears to have ipso facto dramatically shifted the paradigm of protection. The present findings are consistent with and extend those of prior studies demonstrating that the Protego radiation shield provides exceptional protection to the physician operator. The level of validated protection is sufficient to support the concept that this comprehensive radiation shielding system employed provides exceptional operator protection, a magnitude of protection already validated by the Michigan Occupational Safety and Health Administration to be used in lieu of and, therefore, eliminate the need for orthopedically burdensome lead aprons.[17] Occupational Safety and Health Administration Federal standards[30] set the maximum annual allowable occupational RE at 5 rem/annum (5000 mrem/annum). Extrapolating from the present mean waist per case RE data (employing the standard mathematical conversion of microsievert to millirem per case), a structural interventionalist could perform 100 cases/y and be exposed to only approximately 0.14% of allowable limits. Taken further, a "high volume" interventionalist could perform 500 such cases and still be exposed to <1% of the recommended allowable limit.

Limitations

The magnitude of reduction of operator RE in the Protego arm is consistent with the findings of prior studies in coronary procedures documenting the superiority of protection afforded, both in absolute terms and compared to traditional shielding methods. Regardless, it is important to emphasize the observational nature of this study, which may be limited by selection bias and confounding variables. Further studies in structural cases will be necessary to confirm the present findings.

Higher radiation dose (fluoroscopy time, air kerma, and dose area product) was observed in the Protego group despite lower body mass index. Importantly, there is no reason to ascribe such observations to the ergonomics of working with the Protego shield because one of its features is that once set up, the procedure proceeds without any necessity to navigate around or manipulate the shield for C-arm angulations or any other aspect of the operation. Importantly, these differences were neither accounted for by procedural or patient factors nor statistically significantly different.

The present Protego system is not designed to reduce RE to interventional echocardiographers and anesthesiologists working at the head of the table on the "unprotected" side of the shield. Future device iterations will be necessary to afford optimal protection to the entire team. Similarly, when alternate access is required for TAVR, the operators may also be working on the "exposed" side of the shield. Enhanced protection for those procedures and analogous site access procedures in electrophysiology (pacemaker and implantable cardioverter-defibrillator implantations) is also needed. Further study is required to determine whether routine use of this shield system will reduce maladies attributable to occupational hazards, including direct radiation–related injuries (cataracts and cancer) and indirect orthopedic afflictions.

Conclusions

The Protego radiation shielding system provides comprehensive RE protection during structural heart procedures. By achieving a magnitude of protection that allows procedural performance without the need for orthopedically burdensome personal leaded aprons, this shield has potential to reduce occupational injuries.

Peer review statement

Section Editor David G. Rizik had no involvement in the peer review of this article and has no access to information regarding its peer review. Full responsibility for the editorial process for this article was delegated to Associate Editor Andrew M. Goldsweig.

Declaration of competing interest

James Goldstein is an owner of equity and a board member of ECLS, Inc, which licenses technology to Image Diagnostics Inc, which manufactures and sells the Protego shield. David Rizik, Robert Burke, Sabrina Klassen, Ariana Nigoghosian, Robert Riley, and Kevin Gosselin reported no financial interests.

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Ethics statement and patient consent

The research reported has adhered to the relevant ethical guidelines; patient consent has been obtained, if needed.

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